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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,863	09/28/2001	Jeffrey A. Wolk	100/06110	7390
21569 75	90 12/13/2005		EXAM	INER
CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE			OLSEN, ALLAN W	
	VIEW, CA 94043-2234		ART UNIT	PAPER NUMBER
			1763	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Appl	ication No.	Applicant(s)			
Office Action Summary		09/9	966,863	WOLK ET AL.			
		Exar	miner	Art Unit			
		Allan	Olsen	1763			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)⊠	Responsive to communication(s) filed on <u>14 November 2005</u> .						
2a) <u></u> ☐	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
5)□ 6)⊠ 7)□	Claim(s) 1-14 is/are pending in the application.  4a) Of the above claim(s) 3,4 and 10-13 is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) 1,2,5-9 and 14 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election requirement.						
-	on Papers		·				
9) ☐ The specification is objected to by the Examiner.  10) ☑ The drawing(s) filed on 28 September 2001 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.  37 CFR 1.78.  a) The translation of the foreign language provisional application has been received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.							
Attachment(s)							
1) Notice 2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO nation Disclosure Statement(s) (PTO-1449) Pap		5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)			

#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 14, 2005 has been entered.

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-9 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,605,472 issued to Skinner et al. (hereinafter, Skinner).

Skinner teaches a method of forming a microfluidic device by etching channels in a first substrate then bonding a second, overlying substrate to the first substrate.

Skinner teaches drilling an aperture into the first and second substrates so that a capillary may be inserted so as to be in fluid communication with the etched microchannels. Skinner teaches co-axially aligning a drill bit with an etched micro-channel.

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Skinner teaches bringing the drill bit up against an end of a channel (column 14, lines 59-65) that has been made easier to visualize by a polishing step (column, lines 44-45). Skinner teaches drilling in such a manner that the drill bit follows channel (column 9, lines 12, 13). As such, Skinner's etched micro-channel is functioning as applicant's claimed an alignment feature. Skinner teaches forming an additional alignment structure as well with a preliminary drilling step that involves removing only a small amount of material by briefly contacting the drill to the substrate surfaces. The drill is then removed from the substrates for an inspection to verify whether or not a proper alignment was achieved. This preliminary etching step provides an alignment structure for the subsequent, deep drilling steps.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,224,830 issued to Harrison et al. (hereinafter, Harrison)

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Harrison teaches drilling an aperture in a first substrate layer of a microfluidic device. Harrison teaches bonding a first a d second substrate layers together such that an aperture in the second substrate layer corresponds to the aperture in the first substrate layer. Harrison teaches inserting a capillary element into the aperture.

Harrison does not teach aligning the drill with an alignment structure in the first substrate.

It would have been obvious to one skilled in the art to align the drill with an alignment structure because the skilled artisan would readily appreciate that the micro scale of Harrison's channels would necessitate very accurate drilling. As in the previous Office action, the examiner takes Official Notice that the use of an alignment structure (e.g., marking, pilot or guide hole) is a well known and widely used, fundamental drilling technique. Further discussion, with support for the Official Notice follows is provided in the Response to Arguments.

### Response to Arguments

Applicant's arguments filed November 14, 20056 have been fully considered but they are not persuasive.

Applicant argues that Harrison does not teach fabrication an alignment structure in a surface of a first substrate layer or aligning a tool with the alignment structure.

These deficiencies of Harrison were acknowledged by the examiner in the 103 rejection made in the Office action mailed August 112, 2005. As noted by applicant in

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their remarks relies on an official notice that the use of an alignment is a fundamental technique associated with drilling.

Applicant argues that when working in the realm of microfluidic devices, one cannot necessarily adopt the use of standard (i.e., macro) machining techniques, such as using an alignment structure when drilling. As such, applicant maintains that it is not obvious to use macro-machining techniques in micromachining application. Further, applicant notes that the examiner provided no evidence to support of the Official Notice.

In reply, the examiner offers the following to support of the Official Notice. First, the examiner again notes Skinner's use an alignment structure in conjunction with a micro-machining process. Secondly, an assortment of references is provided which demonstrates that there is no barrier between macro machining and micro-machining with respect to the use of forming an alignment structure when drilling. The subject matter of the cited references cover a wide range and includes using alignment structures in the realm of micro-machining as it pertains to; surgical techniques and the fabrication of printing plates, printed circuit boards, photolithographic masks, solar panels and microfluidic devises as well. Note, for example, from 5,950,633:

"As illustrated in FIG. 6, a single pilot hole 38 may be made through each of the frontal scalp incisions 12-18 using a drill bit 40 on 9a hand-held power drill 42. Generally, the drill bit 40 has a diameter 44 of less than 2.0 mm and a stop length 46 of less than 5.0 mm. In one embodiment, the drill bit has a diameter 44 of about 1.7 mm"

It is also worth noting that Harrison states, the "[u]se of photolithographic methods facilitates alignment of the through holes with the flow channels" (column 11, line 48-49). The examiner notes that this statement is made without any elaboration as to

exactly how such techniques may be used, but this suggestion leaves little to the imagination with regard to forming an alignment structure. The use of photolithographic techniques to form alignment structures is also discussed in the references being made of record (see, for example US 5,908,719 and 6,143,152)

Applicant also argue that because Harrison offers a method that is an alternative to "careful machining", Harrison actually "teaches away" from applicant's claimed method of forming an alignment structure.

The Examiner respectfully disagrees with the view that Harrison actually teaches away from careful machining practices. While Harrison's method is intended to ease the precision tolerances, the examiner find nothing in Harrison that goes so far as to say, one should not use careful machining practices (i.e., actually teaches away from such practices).

Applicant's arguments pertaining to Skinner were addressed in the above 102 rejection.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allan Olsen whose telephone number is 571-272-1441. The examiner can normally be reached on M-F 1-5.

<sup>&</sup>lt;sup>1</sup> The examiner notes that Harrison teaches drilling a hole having a diameter of 1.9 mm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Parviz Hassanzadeh can be reached on 571-272-1435. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MaDla

Allan Olsen Primary Examiner Art Unit 1763